K120199

BECKMAN COULTER

OCT 12 2012

510k Summary
AU® Systems HbA1c (Hemoglobin) Test System

1.0 **Submitted By:**

Bev Harding
Sr. Regulatory Affairs Specialist
Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821
Telephone: 972-831-3656
Fax: 972-831-3684
Email: bbharding@beckman.com

2.0 **Date Submitted:**

January 20, 2012

3.0 **Device Name(s):**

3.1 **Proprietary Names**
AU® Systems HbA1c (Hemoglobin) Test System

3.2 **Classification Name**
Glycosylated hemoglobin assay (21 CFR § 864.7470)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
AU® Systems HbA1c (Hemoglobin) Test System	SYNCHRON Systems Hemoglobin A1c (HbA1c) Reagent	Beckman Coulter, Inc	K010748

5.0 **Description:**

The HbA1c assay (B00389) involves the use of four reagents: Total Hemoglobin R1, HbA1c R1, HbA1c R2, and Hemolyzing Reagent (sold separately as Cat. No. 472137). In a pre-treatment step, whole blood is mixed with the Hemolyzing Reagent in a 1 to 100 dilution and the resultant hemolysate is used. Tetradecyltrimethylammonium bromide (TTAB) in the Hemolyzing Reagent eliminates interference from leukocytes.

The concentrations of both HbA1c and Total Hemoglobin are determined. The HbA1c/Total Hemoglobin ratio is expressed either as mmol/mol (IFCC) or %HbA1c (DCCT/NGSP). Total Hemoglobin Reagent is used to measure total hemoglobin concentration by a colorimetric method. Change is absorbance is measured at 570/660 nm. HbA1c reagent is used to measure hemoglobin A1c concentration by a turbidimetric immunoinhibition method. In the reaction, hemoglobin A1c antibodies combine with HbA1c from the sample to form soluble antigen-antibody complexes. Polyhaptens from the reagent then bind with the excess antibodies and the resulting agglutinated complex is measured turbidimetrically. Change in absorbance is measured at 340/700 nm.

6.0 **Intended Use:**

The HbA1c (Hemoglobin A1c) reagent, when used in conjunction with Beckman Coulter Systems, HbA1c Calibrators, and SYNCHRON and AU Hemolyzing Reagent, is intended for the quantitative determination of hemoglobin A1c concentration in human whole blood. For *In Vitro* Diagnostic Use only.

The absolute HbA1c and Total Hemoglobin (THb) values generated as part of the HbA1c assay are intended for use in the calculation of the HbA1c/Total Hemoglobin ratio and must not be used individually for diagnostic purposes.

The HbA1c Calibrators are an in vitro diagnostic product for the calibration of the hemoglobin A1c (HbA1c) method on the AU clinical chemistry systems.

Measurement of hemoglobin A1c is accepted as a method to measure long-term glucose control in patients with diabetes mellitus.

Clinical Significance:

Measurement of hemoglobin A1c is accepted as a method to measure long-term glucose control in patients with diabetes mellitus (a chronic disorder associated with disturbances in carbohydrate, fat, and protein metabolism and characterized by hyperglycemia). Determination of hemoglobin A1c provides an important tool for monitoring the efficiency of dietary control and therapy during treatment of diabetes mellitus. Long term treatment of the disease emphasizes control of blood glucose levels in preventing the acute complications of ketosis and hyperglycemia. In addition, long term complications such as retinopathy, neuropathy, and cardiovascular disease can be minimized if blood glucose levels are effectively controlled.

The process of conversion from hemoglobin A to hemoglobin A1c depends on the blood glucose concentration. Since the average life of a red blood cell is 120 days, measurement of hemoglobin A1c can reflect the mean daily blood glucose concentration over the preceding two to three months and provides a much better indication of glycemic control than blood or urinary glucose determinations.

Beckman Coulter, Inc.
250 S. Kraemer Boulevard
Brea, CA 92821

Telephone: (714) 993-5321
Facsimile: (714) 961-4234
Internet: www.beckmancoulter.com

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicate identified in Section 4.0 of this summary.

Feature	Predicate Device: K010748	New Device:	Similarities
Intended Use	The hemoglobin a1c reagent kit, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s), SYNCHRON® Systems HbA1c Calibrators and SYNCHRON® Systems Hemolyzing Reagent, **is intended for the quantitative determination of hemoglobin a1c concentration** as a percentage of total hemoglobin **in human wholeblood.**	The HbA1c (Hemoglobin A1c) reagent, when used in conjunction with Beckman Coulter Systems, HbA1c Calibrators and SYNCHRON and AU Hemolyzing Reagent, is **intended for the quantitative determination of hemoglobin A1c concentration in human whole blood.** For in *vitro* diagnostic use only. The absolute HbA1c and Total Hemoglobin (THb) values generated as part of the HbA1c assay are intended for use in the calculation of the HbA1c/Total Hemoglobin ratio and must not be used individually for diagnostic purposes.	Similar
Technology	Colorimetric	Colorimetric	Same
Methodology	Turbidimetric immunoinhibition	Turbidimetric immunoinhibition	Same
Specimen Type	Whole blood	Whole blood	Same
Packaging	Reagents and calibrators in kit; Hemolyzing reagent sold separately.	Reagents and calibrators in kit; Hemolyzing reagent sold separately.	Similar
Sample Type	Freshly drawn blood treated with EDTA or heparin is the preferred specimen. Details on EDTA, Lithium Heparin, and Sodium heparin are in IFU.	K_2-EDTA, K_3-EDTA, Li-Heparin or Na-Heparin whole blood (freshly drawn blood treated with EDTA is the preferred specimen).	Similar
Sample Preparation	Before use, pre-treat samples by manual	Before use, pre-treat samples and controls by	Similar

	dilution.	manual dilution.	
Reagent Format and Storage	Liquid Stable 2 - 8°C	Liquid Stable 2 - 8°C	Similar
Calibrator matrix base	Hemolysate (human and sheep)	Hemolysate (human and sheep)	Same
Traceability	IFCC HbA1c Reference Method. Process based on prEN ISO 17511. Data is converted to NGSP units via the use of the Master Equation.	IFCC HbA1c Reference Method. Data is converted to NGSP units via the use of the Master Equation.	Similar
Certification	NGSP certified	NGSP certified	Similar
Reference Interval	Literature 4.0 – 6.0% HbA1c SYNCHRON 4.6-2.6% HbA1c	4.0 – 6.0% HbA1c	Similar Performance data within the submission supports substantial equivalence and reference interval.
Interfering Substances	No significant interference (within ± 0.80% HbA1c or 10%) Bilirubin (unconjugated) 30 mg/dL Lipemia 400 mg/dL RF 3000 IU/ml Ascorbic acid 50 mg/dL Labile glycated hemoglobin ≤10% up to 1000 mg/dL (5 hours at 37°C) Cross reactivity and Hb Variants interference data also presented in IFU.	Bilirubin ≤6% up to 30 mg/dL Lipemia ≤6% up to 400 mg/dL Intralipid® RF ≤6% up to 1000 IU/mL Ascorbic Acid ≤6% up to 50 mg/dL Labile glycated hemoglobin ≤10% up to 2000 mg/dL (5 hours at 37°C) Cross reactivity and Hb Variants interference data also presented in IFU.	Similar

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Feature	Predicate Device:	New Device:	Differences
Precision	Within 5.0% Total 7.5 %	Within 4.0% Total 4.0%	Different Performance data within the submission supports improved precision and substantial equivalence of the new test system.
Analytical Measuring Range	2 - 20% HbA1c	4 – 15% HbA1c (NGSP)/20 - 140 mmol/mol (IFCC)	Different NGSP units are reported as %HbA1c; IFCC units are reported as mmol/mol. Method comparison and linearity data helped support extending the range on the AU HbA1c.
Instrument	SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s), SYNCHRON® Systems	Models of AU analyzers	Different The AU analyzer data within the submission supports the substantial equivalence for AU480, AU680 and the AU2700 Beckman Coulter Analyzers.
Calibrator Format and Levels	Lyophilized 5 levels Hb = single point A1c = multi point	Lyophilized 5 levels THb = two point HbA1c = multi point	Different The number of calibrators used is method-specific. Performance data within the

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			submission supports substantial equivalence of the calibrators and new reagents.
Pre-treatment Reagent	SYCHRON Hemolyzing Reagent 1000 uL hemolyzing reagent in test tube Add exactly 10 uL of whole blood sample	SYCHRON and AU Hemolyzing Reagent Ratio 1 to100 dilution Pre-treatment – until hemolysis is complete (approx. 1-2 minutes).	Different Performance data within the submission supports substantial equivalence.
Stability	Calibrator & Reagent unopened store at 2° to 8°C until expiration date Calibrator reconstituted = 8 hours 15°- 25°C 48 hours at 2°- 8°C unless expiration date is exceeded Open hemoglobin reagent stable 60 days at 2°-8°C unless exp. date exceeded. Open A1c reagent stable 30 days at 2°- 8°C unless exp. date exceeded.	Calibrator & Reagent unopened store at 2° to 8°C until expiration date Calibrator reconstituted = up to 8 hours at 15 - 25°C up to 30 hours at 2 – 8°C up to 30 days at - 20 °C. Calibration Stability = 14 days Reagent on-board = 30 days Kit Shelf Life Stability = 18 months at launch	Different Stability data within the submission supports new claims.
Reporting Units	SYNCHRON calculations IFCC HbA1c concentration in percent. Must use calculation in IFU that converts IFCC to NGSP.	% HbA1c (NGSP) and mmol/mol (IFCC)	Different IFCC /IUPAC committee updated their recommend-ations on HbA1c units and nomenclature in 2007.
Sensitivity	Sensitivity is defined as the lowest measurable concentration which can be distinguished from	THb: LoB = 0.05 mmol/L (0.09 g/dL); LoD = 0.10 mmol/L (0.16	Different Sensitivity for the new device

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	zero with 95% confidence. Sensitivity for the total hemoglobin determination is 6 g/dL. Sensitivity for the A1c determination is 0.3 g/dL.	g/dL). HbA1c: LoB = 0.12 mmol/L (0.19 g/dL); LoD = 0.13 mmol/L (0.22 g/dL).	refers to LoB and LoD, rather than general sensitivity. Performance data within the submission supports substantial equivalence and new claim.
Specimen Storage and Stability	Whole blood samples stable for: No longer than 7 days at 2 - 8°C 3 months at -15 C to -20°C Hemolysate stable 4 hours at room temperature and 24 hours at 2° to 8°C	Samples (non-pretreated) are stable up to 8 hours when stored at 25°C, 7 days when stored at 2...8°C and up to 3 months when frozen at -20°C. Whole blood samples are stable for 18 months at -70°C Hemolyzed (pre-treated) samples are stable up to 4 hours when stored at 15...25°C, up to 24 hours when stored at 2...8°C, if stored in a sealed container.	Different Stability data within the submission supports substantial equivalence and new claims.

8.0 **Summary of Performance Data:**

Based on the performance testing the AU® Systems HbA1c (Hemoglobin) Test System is substantially equivalent to the predicate device.

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Method Comparison Study Results

Candidate	Slope	Intercept	R	N	Predicate Method
AU HbA1c Test System	0.901	0.3140	0.9941	130	SYNCHRON Systems Hemoglobin A1c (HbA1c) Reagent

AU HbA1c Test System Precision Study Results

TYPE OF IMPRECISION	SAMPLE TYPE	No. of Data Points	Mean %HbA1c	CV%	SD (%HbA1c)
Within run	Hemolysate Control Pool 1	80	5.3	1.44	0.08
	Hemolysate Control Pool 2	80	7.4	1.03	0.08
	Hemolysate Control Pool 3	80	9.4	1.03	0.10
Total	Hemolysate Control Pool 1	80	5.3	2.07	0.11
	Hemolysate Control Pool 2	80	7.4	1.84	0.14
	Hemolysate Control Pool 3	80	9.4	1.68	0.16

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Beckman Coulter, Inc
c/o Beverly Harding
250 S. Kraemer Blvd.
Mail Stop A2 SW.08
Brea, California 92821

OCT 12 2012

Re: k120199
Trade Name: AU® Systems HbA1c (Hemoglobin A1c) Test System
Regulation Number: 21 CFR §864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Codes: LCP, JIT
Dated: September 11, 2012
Received: September 13, 2012

Dear Ms. Harding:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Devices and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH'S Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-576-. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800 638-2041 or (301) 796-5680 or at its Internet address http://www.fda/gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K120199

Device Name: AU® Systems HbA1c (Hemoglobin A1c) Test System

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Measurement of hemoglobin A1c is accepted as a method to measure long-term glucose control in patients with diabetes mellitus.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120199